ACUITY™ Universal Cutter 510(k) Submission
Attachment D

510(K) SUMMARY K080154

MAR 20 2008

Submitter:	Boston Scientific Corporation Cardiac Rhythm Management (CRM) 4100 Hamline Avenue North St. Paul, Minnesota 55112-5498
Contact:	Kathleen Vittum Regulatory Affairs Specialist
Telephone:	(800) 227-3422 or direct (651) 582-4820
FAX:	(612) 582-5134
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Date of Summary:	January 17, 2008
Trade Name:	ACUITY™ Universal Cutter
Common Name:	Cutter
Classification Name:	Catheter Guide Wire, (21 CFR 870.1250, Product Code DQY)
Predicate	RAPIDO™ Cut-Away™ Cutter (K031459, cleared 07/23/2003)

1. **Device Trade Name**
   ACUITY™ Universal Cutter

2. **Device Common Name**
   Cutter

3. **Device Description**

   The Cutter is an accessory manufactured for use with cuttable guiding catheters, to facilitate removal of the catheter following lead placement. The Cutter attaches to the lead and cuts one wall of the guiding catheter as it is removed from the patient, allowing the guiding catheter to be removed from the lead. The Cutter consists of three sections: a molded plastic handle, a stainless steel blade and a lead management section. The lead management section secures and stabilizes the lead prior to and during the cutting procedure. After the lead has been positioned in the patient, the cutter is connected to the lead body as close to the catheter hub as possible. Holding the cutter stationary and fixed to a surface, the implanter pulls the catheter against the cutter blade. The hub is cut first, followed by the catheter section.

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4. Intended Use

The Universal Cutter is intended to be used with Guidant or Boston Scientific cuttable families of guiding catheters, and is intended to facilitate guiding catheter removal after the Guidant or Boston Scientific coronary venous lead is positioned.

5. Technological Characteristics

Comparisons of the Universal Cutter and predicate devices show that the technological characteristics such as design and intended use are substantially equivalent to the currently marketed predicate device (RAPIDO Cut-Away Cutter).

6. Performance Data

Testing demonstrates that the Universal Cutter meets the acceptance criteria and performs similarly to the predicate device. No new safety or effectiveness issues were raised during the testing program. The Universal Cutter may be considered substantially equivalent to the predicate device.

7. Conclusion

Boston Scientific's ACUITY™ Universal Cutter is substantially equivalent to the currently marketed Guidant RAPIDO Cut-Away Cutter (K031459, cleared 07/23/2003) with regard to intended use and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 2008

Boston Scientific Corporation
c/o Ms. Kathleen Vittum
Cardiac Rhythm Management (CRM)
4100 Hamline Avenue North
St. Paul, MN 55112-5798

Re: K080154
Trade/Device Name: Acuity™ Universal Cutter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: March 4, 2008
Received: March 5, 2008

Dear Ms. Vittum:

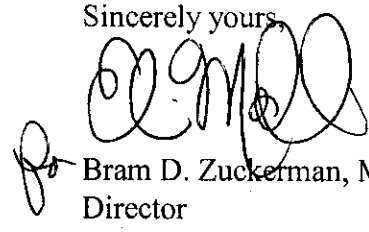
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K080154

Device Name: **ACUITY™ Universal Cutter**

Indications For Use: The Boston Scientific ACUITY™ Universal Cutter is intended to be used with Guidant or Boston Scientific cuttable families of guiding catheters, and is intended to facilitate guiding catheter removal after the Guidant or Boston Scientific coronary venous lead is positioned..

Prescription Use: [X] AND/OR Over-The-Counter Use: [ ]

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080154